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HHS Public Access

Author manuscript

AIDS Behav. Author manuscript; available in PMC 2015 November 23.

Published in final edited form as:

AIDS Behav. 2014 July ; 18(7): 1390–1400. doi:10.1007/s10461-014-0712-4.

Adapted Personalized Cognitive Counseling for Episodic Substance-Using Men Who Have Sex with Men: A Randomized Controlled Trial

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Conflict of interest Authors declare no conflicts of interest.

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Abstract

Episodic drug use and binge drinking are associated with HIV risk among substance-using men who have sex with men (SUMSM), yet no evidence-based interventions exist for these men. We adapted personalized cognitive counseling (PCC) to address self-justifications for high-risk sex among HIV-negative, episodic SUMSM, then randomized men to PCC (n = 162) with HIV testing or control (n = 164) with HIV testing alone. No significant between-group differences were found in the three primary study outcomes: number of unprotected anal intercourse events (UAI), number of UAI partners, and UAI with three most recent non-primary partners. In a planned subgroup analysis of non-substance dependent men, there were significant reductions in UAI with most recent non-primary partners among PCC participants (RR = 0.56; 95 %CI 0.34–0.92; *P* = 0.02). We did not find evidence that PCC reduced sexual risk behaviors overall, but observed significant reductions in UAI events among non-dependent SUMSM. PCC may be beneficial among SUMSM screening negative for substance dependence.

Keywords

HIV prevention; Evidence-based intervention; Cognitive counseling; Adaptation; Substance use; MSM

Introduction

Although men who have sex with men (MSM) represent 4 % of the U.S. male population [1], they accounted for 78 % of all new HIV infections among males and 63 % of all new infections in the United States in 2011 [2]. In San Francisco, MSM accounted for 82 % of new HIV infections in 2011 [3]. Among MSM nationally [4], and in San Francisco [3], HIV prevalence is 3–6 times as high among blacks/African Americans and Latinos compared to whites. Drug and alcohol (“substance”) use occurs disproportionately among MSM [5–8], and substantially increases HIV risk when occurring just before or during sex [9–11]. Across MSM populations, methamphetamine, amyl nitrate (poppers), cocaine, and heavy alcohol use are the substances most consistently associated with high-risk behaviors and disease incidence, including unprotected anal intercourse (UAI), high numbers of sexual partners,

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HIV seroconversion, sexually transmitted infections, and condom slippage or breakage [9–19]. These substances have several effects, including increased libido, sexual confidence, sense of invulnerability, expectancies of cognitive escape and sexual satisfaction, and impaired judgment. Each of these effects can be associated with high-risk sexual practices [20–24].

The relationship between substance use and HIV risk is further complicated by differences in frequency of use and polysubstance use. HIV transmission risk is positively associated with severity and frequency of substance use and related to concomitant use of multiple substances [25]. Many substance-using MSM (SUMSM) use substances recreationally and less than weekly (i.e., “episodically”); however, few use only one substance [25]. In the National HIV Behavioral Surveillance study, 69–86 % of SUMSM reported less than weekly substance use [26–29]. In San Francisco, less than weekly use was reported by 76 % of methamphetamine users, 79 % of poppers users, 86 % of cocaine users, and 62 % of crack users [30]. In a study of circuit parties, SUMSM reported a median of 3.5 drugs used during circuit party weekends, but fewer than 5 % reported use of any illicit substances during non-event weekends [12]. Many episodic SUMSM report sex and substance use “always” or “often” go together, and qualitative studies show that MSM use substances specifically to perform sexual acts [21, 31–33]. Whereas the heaviest substance users carry the greatest individual risk for HIV transmission, the larger population of episodic users may present a greater population-level risk for transmission. Moreover, as episodic SUMSM may not identify a problem with their use and may not require or access intensive therapy, tailored behavioral interventions may be effective in reducing sex and drug risk.

Nine HIV prevention interventions were classified by the Centers for Disease Control and Prevention (CDC) as demonstrating best-evidence of intervention efficacy in reducing HIV-related risk behaviors among MSM [34]. However, none of these interventions address co-occurring substance use and sexual risk associated with HIV transmission. Given the high rate of episodic substance use among MSM, its link with sexual risk, and paucity of proven interventions for episodic SUMSM, it is important to adapt existing interventions for this high-risk population [35]. The personalized cognitive counseling (PCC) intervention [36], which CDC has identified as a “best evidence” intervention, was adapted for episodic SUMSM because it demonstrated a strong and sustained effect in reducing number of UAI episodes with partners of HIV-positive or unknown serostatus in two randomized trials [37, 38]. PCC involves a brief counseling session, and is acceptable in a general population of MSM [37, 38] and among MSM of color [39]. PCC is predicated on the hypothesis that many HIV-negative MSM who take risks do so despite knowing the potential for HIV infection.

The three-phase process used to adapt PCC for episodic SUMSM is described elsewhere [40]. To briefly summarize, phase 1 involved in-depth interviews with 20 episodic SUMSM to identify and abstract relevant self-justifications for unprotected anal intercourse and concurrent substance use. Self-justifications were compared to self-justifications from the original PCC instrument to determine which of the original self-justifications to retain and which new items to add. Criteria for the creation of new items included linkage of alcohol and/or other drug use to UAI, frequency of theme occurrence across participants, and topics

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that would resonate for a wide range of MSM (e.g. transmission risk calculus). The adapted self-justification elicitation instrument (SJEI) included 17 items retained from the original PCC SJEI and 31 newly developed items. Nine themes related to self-justifications emerged from the in-depth interviews: [1] substance use as facilitator of risk, [2] transmission risk calculus, [3] assumptions regarding partner's HIV status, [4] cognitive escape, [5] sensation seeking/spontaneity, [6] condom-related issues, [7] opportunities for sex, [8] expectations or obligations for unprotected sex, and [9] feelings of invincibility. Phase 2 involved pre-testing the adapted SJEI with 19 episodic SUMSM to determine relevance and representativeness of self-justification items. During this phase we also elicited participant comments about the adapted SJEI. Participants appreciated the informal language used as well as the comprehensiveness and utility of the instrument. Phase 3 of the adaptation process involved pilot testing the complete PCC intervention session with 20 episodic SUMSM to determine feasibility and acceptability. Participants filled out the SJEI and then met with a counselor for a PCC session. Afterwards, participants were invited to critique the SJEI and the counseling process. Participants in the pilot test phase reported similar positive feedback as those in the pre-test phase. Feedback from pretesting of the adapted SJEI and pilot testing was incorporated in the final adapted PCC.

In this paper, we report findings on the efficacy of the adapted PCC intervention for reducing HIV-related sexual risk behaviors among ethnically diverse, HIV-negative, episodic SUMSM. We hypothesized that episodic SUMSM who receive the adapted PCC and rapid HIV testing would report greater reductions in number of unprotected anal intercourse (UAI) events, number of unprotected UAI partners, and number of UAI events with three most recent non-primary partners than men receiving rapid HIV testing only.

Methods

Between May 2010 and May 2012, we recruited episodic SUMSM who engaged in sexual activity that increased their risk of HIV acquisition, specifically high-risk UAI while under the influence of alcohol and other drugs. The definition for "episodic" substance use was derived from prior research studies of MSM conducted in San Francisco [11, 41]. Recruitment involved street outreach at community venues in San Francisco, including outside of bars, clubs, grocery stores, gyms, and other venues frequented by MSM. To recruit a racially and ethnically diverse sample of episodic SUMSM, recruitment also occurred at community-based organizations serving African American, Latino, and Asian and Pacific Islander MSM. For venue-based recruitment, study recruiters informed potential participants of the study, emphasized that participation was voluntary, and provided flyers describing the study.

Potential participants completed a brief telephone screening to assess initial eligibility and, if eligible, were scheduled for in-person re-screening visits. Eligible participants: (a) reported UAI with another man while under the influence of at least one or any combination of the following substances: methamphetamine, poppers, crack or powder cocaine, or alcohol if binge drinking (five or more drinks) within 2 h before or during sex within the past 6 months; (b) identified as male; (c) were HIV-negative or unknown serostatus by self-report; (d) were willing and able to participate in an intervention that addresses episodic substance

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use and sexual risk behavior; (e) were not currently in substance use treatment, a self-help program, an HIV prevention study, or receiving prophylaxis treatment; (f) had not injected any substances in prior 6 months; (g) were 18 years of age or older; (h) were planning to remain in the San Francisco Bay Area for the duration of study activities; and (i) were able to speak, read, and understand English. Men were ineligible if they reported UAI during the past 6 months with only one primary partner; and reported weekly or more use of any of the targeted substances in the prior 3 months or, for alcohol, more than an average of three alcoholic drinks daily or binge drinking more than twice weekly. Men who reported use of "club drugs" such as ecstasy, ketamine, and GHB were not excluded from the study as long as they also reported use of the target substances. Ineligible participants were provided information about community referrals for more intensive substance use treatment. All participants provided informed consent to participate in the study and the protocol was approved by the University of California Committee on Human Research. The study is registered on www.clinicaltrials.gov (NCT01279044).

Baseline and Follow-up Visits

During the initial study visit, all eligible participants were rescreened for eligibility, provided informed consent, and completed a baseline assessment using audio computer-assisted self-interview (ACASI) technology to standardize data collection and minimize reporting bias [42]. Participants were informed that they could be randomized to the PCC arm or the control arm (the exact language in the informed consent document was "Half the men enrolled in this study will be selected by a computer to meet with a counselor during their visit. You will have an equal chance of being placed in this group or in the group that does not meet with a counselor."). Eligible participants were then randomly assigned to either the PCC intervention arm or control arm (i.e., rapid HIV testing and information describing HIV test procedures and transmission). A one-to-one random allocation sequence was generated using a SAS computer program; allocations were in a fixed-block size of four. To ensure balanced study arms in terms of race/ethnicity and age, randomization was stratified into four groups: [1] African American participants age 25 and under, [2] African Americans over 25 years old, [3] Non-African American participants age 25 and under, [4] Non-African American participants over 25 years old. Staff members who had no contact with study participants enclosed and sealed treatment allocation cards in sequentially numbered opaque envelopes to correspond with the randomization sequence. As a participant was enrolled, the envelope that corresponded with their sequence was opened to reveal their randomized treatment condition.

All participants seen at baseline and at 3- and 6-month follow-up visits received a rapid HIV test following CDC's guidelines for HIV testing in health care settings [43]. In both study arms, persons testing positive by the rapid test received a confirmatory Western Blot assay performed by the CLIA-certified laboratory at the San Francisco Department of Public Health. Newly diagnosed participants received counseling about their HIV positive antibody test, the importance of mobilizing support, and risk-reduction counseling. Referrals were made for services and health care, including San Francisco clinics specializing in treating new HIV cases, and assistance provided to make appointments as needed. All project

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counselors were trained and certified in HIV testing and counseling, and attended refresher courses every 6–12 months.

Participants received reminder phone calls and/or emails prior to each study visit, and were remunerated $35 for the baseline assessment, $40 for the 3-month assessment, and $50 for the 6-month assessment. All study procedures were conducted in private counseling rooms at the San Francisco Department of Public Health.

Intervention

PCC is based on the hypothesis that many MSM who take risks do so despite knowing the potential for HIV infection, and is guided by Bandura's theory of self-regulation [44, 45], DiClemente and Prochaska's stages of behavior change [46, 47], and Gold and colleagues' concept of self-justifications for high-risk sexual behaviors among MSM [48]. The 30–50-min PCC session involved five key counselor-guided activities and was adapted for episodic substance using MSM [40]. In each PCC session the participant recalled a recent memorable encounter of UAI with another man of unknown or serodiscordant HIV status and used that salient event to complete a paper SJEI with pre-worded statements [40] to elicit the specific self-justifications used to minimize the known sexual risk that permitted him to proceed with UAI and prepare for a detailed discussion of the event. The counselor encouraged the participant to identify and express any thoughts, feelings or attitudes that may have led to the high-risk sexual encounter and aided the participant in clarifying which of the selected self-justifications led to risky behavior. The participant then explored strategies to avoid similar high-risk situations in the future, including reframing self-justifications to clarify the reality of risk. The counseling allowed participants to re-examine the function of self-justifications they utilized when making a decision to engage in high-risk sex, reappraise the level of risk that occurred, and modify self-justifications or generate alternative self-statements that might reduce sexual risk in the future [37, 38]. Counseling sessions were taped and selected sessions were reviewed for fidelity.

After completing their 3-month follow-up assessment, intervention participants received one of three types of booster counseling sessions tailored to their interim level of risk: [1] if the participant reported UAI with a different partner than at baseline, he completed the SJEI and received PCC; [2] if the participant reported UAI with the same partner as at baseline, he did not receive the SJEI and PCC but received counseling regarding explicit communication about HIV status and risk that occurred between participant and partner to identify assumptions about risk and efforts the participant could make to reduce his HIV risk in the current relationship; or [3] if the participant reported only protected anal intercourse or no anal intercourse in the past 3 months, he received neither the SJEI nor PCC but a general counseling session focused on reasons for protected or no anal intercourse, who initiated protection, feelings/thoughts around reduced sexual risk, and ways to continue reducing sexual risk.

Table 1 includes the most common self-justifications endorsed by PCC participants at baseline and 3-month booster sessions with within-person concordance for each self-justification between the two visits. We collected no qualitative or quantitative data around

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self-justification stability/fluidity to support any hypothesis as to the reason for rates of concordance.

Measures

Sexual risk behavior measures—Measures included number of sex partners and number of unprotected receptive and insertive anal intercourse events in the prior 3 months. UAI events were asked for primary and three most recent non-primary partners [11]. *A priori* primary study outcomes include number of UAI events, number of UAI partners, and number of UAI events with three most recent non-primary partners. Secondary outcomes included number of serodiscordant unprotected anal intercourse (SDUAI) events with non-primary partners (i.e., the outcome used in the original PCC efficacy studies [37, 38]), number of condom-protected anal intercourse events, and number of insertive and receptive UAI events.

Substance dependence—Self-reported data on the five-item severity of dependence scale (SDS) [49], a validated measure of symptoms of substance dependence, was collected for each of the target substances: methamphetamine, poppers, cocaine and alcohol. Calculated SDS scores had high internal validity and consistency; Cronbach's alphas for SDS scores on methamphetamine, poppers, cocaine and alcohol were 0.80, 0.73, 0.85 and 0.86, respectively. In previously published validation studies, an SDS score of 4 or more was indicative of methamphetamine dependence [50], and an SDS score of 3 or more was indicative of dependence on cocaine and alcohol [51, 52]. We did not find a published SDS cut-off for poppers so poppers use dependence was classified as a SDS score of 3 or more, the most common cut-off among our study's other target substances [51, 52].

Statistical Analysis

To calculate sample size, we assumed (a) a post-randomization relative reduction in outcomes of 10 % among controls due to cohort effects; (b) that numbers of UAI/ SDUAI events as well as partners would be strongly correlated within person [11]; and (c) that 90 % of the sample would attend both follow-up visits. Under these assumptions, a sample of 300–326 participants provided 80 % power to detect relative reductions of 24–38 % in these outcomes, depending on within-subject correlations.

Intention-to-treat (ITT) analyses for primary and secondary outcomes were conducted according to participants' random allocation (PCC = 162; control = 164), without regard to adherence to study procedures, and based on all observed study data. We did not impute missing outcomes; less than 5 % of data was missing due to missed visits and study drop-out. We used generalized estimating equations (GEE) models to evaluate group-specific linear trends outcomes across the three study visits, with robust standard errors to account for within-subject correlation as well as potential over-dispersion of count outcomes. Binary and count outcomes were examined using Poisson and negative binomial models, respectively. In all models, the effect of the intervention was estimated by the interaction between the treatment assignment indicator and a linear term in time. The exponentiated coefficient for interaction is interpretable as the ratio of the intervention and control rates of change in the mean value of the outcome, or rate ratio (RR). The linearity assumption was

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verified for all models. We conducted planned sub-group analyses stratified by any substance dependence for methamphetamine, poppers, cocaine and alcohol at baseline, as measured by the SDS. We also conducted post hoc subgroup analyses stratified by race/ethnicity, both overall and restricted to the non-dependent group.

Results

Sample Characteristics and Retention

Of 2,649 potential participants screened, 431 (16.3 %) met eligibility criteria. Among 2,218 ineligible participants, 32 % reported no substance use during UAI, 29 % reported no UAI with non-primary partner, and 16 % reported no UAI, all during the past 6 months. There were no significant differences between eligible and ineligible participants by age ($z = -0.30$; $P = 0.76$) or race/ethnicity ($\chi^2 = 3.62$; $P = 0.46$); eligible participants were more likely to have had an HIV test during the past year than ineligible participants ($\chi^2 = 21.15$; $P < 0.001$). Among eligible participants, 326 (75.4 %) agreed to participate and were enrolled in the study. Overall, 96 % of participants completed 3- and 6-month follow-up assessments; reasons for attrition are provided in Fig. 1. There were no significant differences in retention by study arm (PCC 94 % and control 98 %; $\chi^2 = 2.76$; $P = 0.10$). There were no study-related adverse events.

There were no significant differences between the two study arms on baseline demographics, HIV testing, and substance use (Table 2). The mean age was 33.6 years; 47 % were white and 53 % non-white including 26 % Latino/Hispanic, 11 % Asian and Pacific Islander, 10 % black/African American, and 6 % mixed/other race. The majority (83 %) was born in the US, 71 % completed some college or had college degree, and 71 % earned over $20,000 per year. A majority of participants (92 %) reported having an HIV test during the past year, 63 % had a regular health provider, and 68 % had either private or public health insurance. Two participants tested HIV-positive at the baseline visit, three at the 3-month visit, and none at the 6-month visit (all were included in analysis per ITT).

Efficacy Analyses

There were no statistically significant differences in baseline sexual risk behaviors between study arms. In intention-to-treat (ITT) analyses, no significant intervention effects were observed for the three primary outcomes, including total number of UAI events, number of UAI partners, and number of UAI events with three most recent non-primary partners; nor for secondary outcomes including number of SDUAI events, condom-protected anal intercourse events, and number of insertive UAI events (Table 3). PCC participants reported borderline significantly greater declines in number of receptive UAI events over the study period than control participants (RR = 0.57; 95 %CI 0.33–1.01; $P = 0.052$).

Sub-group Analyses

A total of 138 participants were classified as substance dependent based on SDS scores, including 7 for methamphetamine, 12 for poppers, 21 for cocaine, and 122 for alcohol. Participants dependent on only one substance included 2 for methamphetamine, 3 for poppers, 10 for cocaine, and 103 for alcohol. There were no significant intervention effects

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on primary or secondary outcomes among these substance-dependent SUMSM. For participants not dependent on any target substance, PCC participants (N = 93) reported significantly greater reductions in number of UAI events with three most recent non-primary partners than control participants (N = 93) (RR = 0.56; 95 %CI 0.34–0.92; *P* = 0.02; Fig. 2). However, there were no significant intervention effects on total number of UAI events (RR = 1.61; 95 %CI 0.79–3.28; *P* = 0.19), total number of UAI partners (RR = 1.09; 95 %CI 0.64–1.86; *P* = 0.76) or number of SDUAI events (RR = 0.57; 95 %CI 0.26–1.22; *P* = 0.15).

In subgroup analyses of SUMSM of color (N = 79 in PCC, N = 92 in control), we did not observe significant intervention effects on the primary outcomes. However, among non-substance dependent SUMSM of color (N = 44 in PCC, N = 51 in control), we observed significant intervention effects in total number of UAI events (RR = 0.41; 95 %CI 0.18–0.95; *P* = 0.04) and UAI events with three most-recent non-primary partners (RR = 0.37; 95 %CI 0.16–0.87; *P* = 0.02).

Discussion

In this randomized controlled trial, we did not find evidence that the adapted PCC intervention was efficacious in reducing sexual risk behaviors among the full cohort of HIV-negative, episodic SUMSM, but did identify a reduction in one primary sexual risk behavior outcome among participants screening as non-dependent on target substances. The significant reduction in number of UAI events with three most recent non-primary partners reflects a moderate effect size, which may correspond with clinically significant reductions in HIV risk among non-dependent, episodic SUMSM. In the full cohort, PCC participants reported a borderline significant trend for greater declines in number of receptive UAI events over the study period than control participants. These findings suggest that the adapted PCC may benefit SUMSM who screen negative for substance dependence by SDS.

Among non-substance dependent men of color, we observed statistically significant reductions in total number of UAI events and number of UAI events with three most recent non-primary partners. Although this analysis was post hoc, the result suggests that PCC may be particularly efficacious among that subgroup. This finding is consistent with a secondary analysis of a prior efficacy trial among MSM of color in which PCC participants reported greater reductions in mean UAI episodes than control participants [39]. Although the sub-group analysis is limited to a small sample of non-dependent SUMSM of color, these findings are important given the lack of efficacious interventions for MSM of color [53, 54] and high HIV incidence in this population [4]. A subsequent evaluation of PCC delivered to SUMSM of color may be an important next step to conclusively validate these findings.

The adapted PCC was intended for episodic SUMSM and involved a brief counseling session plus rapid HIV testing. However, given the degree of substance use reported by participants, it appears some participants were substance-dependent and we would not expect the intervention to affect sexual risk behaviors among substance-dependent MSM. Nonetheless, 42 % of enrolled subjects screened positive for substance dependence, 88 % of whom reported symptoms of alcohol dependence. In an analysis of this study's screener data, we found strong evidence of a dose-response relationship between frequency of

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substance use and HIV-risk; with more severe substance use associated with greater odds of HIV risk [25]. These findings suggest that a sensitive screen for dependence, such as the SDS, may be necessary if this intervention is to be implemented in HIV prevention practice. MSM reporting substance use dependence symptoms should probably be directed to more intensive substance use services. Treating substance dependence among SUMSM would likely elevate the efficacy of HIV prevention interventions, consistent with the syndemic theory [55].

We observed parallel reductions in sexual risk behaviors among those in the treatment and control conditions in the overall sample, which is consistent with other behavioral interventions developed for SUMSM [41, 56]. Some reduction in sexual risk behavior in the control arm would have been expected due to regression to the mean, yet it is reassuring that SUMSM in the control arm also reduced their risk behavior when provided with rapid HIV testing and brief counseling. While there have been intervention trials for SUMSM that have shown reductions in sexual risk overall, these studies randomized participants to different active treatment conditions (i.e., no passive control arm) [57, 58]. To our knowledge only one behavioral intervention significantly increased safer sex behaviors among SUMSM compared to a minimal control group [59]; however, that study was limited to HIV-positive methamphetamine-using MSM. Thus, no behavioral interventions developed for HIV-negative SUMSM have shown efficacy in reducing sexual risk behaviors against a passive control condition, highlighting the limited effectiveness of stand-alone behavioral interventions and the importance of developing combination intervention approaches for SUMSM. Future studies are encouraged to develop and evaluate multi-modal interventions for HIV risk reduction, including combination counseling and pharmacologic interventions [60].

Limitations to the study should be acknowledged. Outcome data were by self-report, although ACASI was used to limit the social desirability bias. In addition, our sample was limited to SUMSM from San Francisco and our findings may not generalize to other locations. As discovered in the analysis, 42 % of the sample screened as dependent on substances according to the SDS, and the inclusion of substance-dependent men reduced our ability to detect significant intervention effects in the overall sample. However, enrolling both dependent and non-dependent episodic SUMSM provided the critical insight that this brief counseling intervention is unlikely to be effective for substance-dependent men. Future research of SUMSM should aim to more rigorously determine the degree of substance dependence prior to enrollment. In addition, the sample size of the subgroup analyses was small, and findings should be viewed as preliminary.

Conclusion

This study demonstrated that the adapted PCC intervention was efficacious in reducing sexual risk behavior among non-dependent, HIV-negative SUMSM, in particular non-dependent men of color. As the HIV epidemic in the USA continues to dramatically and disproportionately affect MSM and episodic SUMSM remain at high risk for HIV infection [25], there is a critical need to develop and evaluate interventions that address multiple facets of risk behavior. Combination approaches for SUMSM are needed to modify high-

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risk behavior, especially when under the influence of drugs and alcohol, and increase awareness for effective substance use treatment.

Acknowledgments

The study was supported by the Centers for Disease Control and Prevention under cooperative agreement UR6PS000684 to Public Health Foundation Enterprises, City of Industry, California. We acknowledge all of the study participants who volunteered for this Project, Project ECHO facilitators and staff (Erin Antunez, Reggie Gage, Alic Shook, Rand Dadasovich, Shannon Huffaker, Deirdre Santos and Kelly R. Knight), the recruitment coordinator, John Farley, and field recruitment team.

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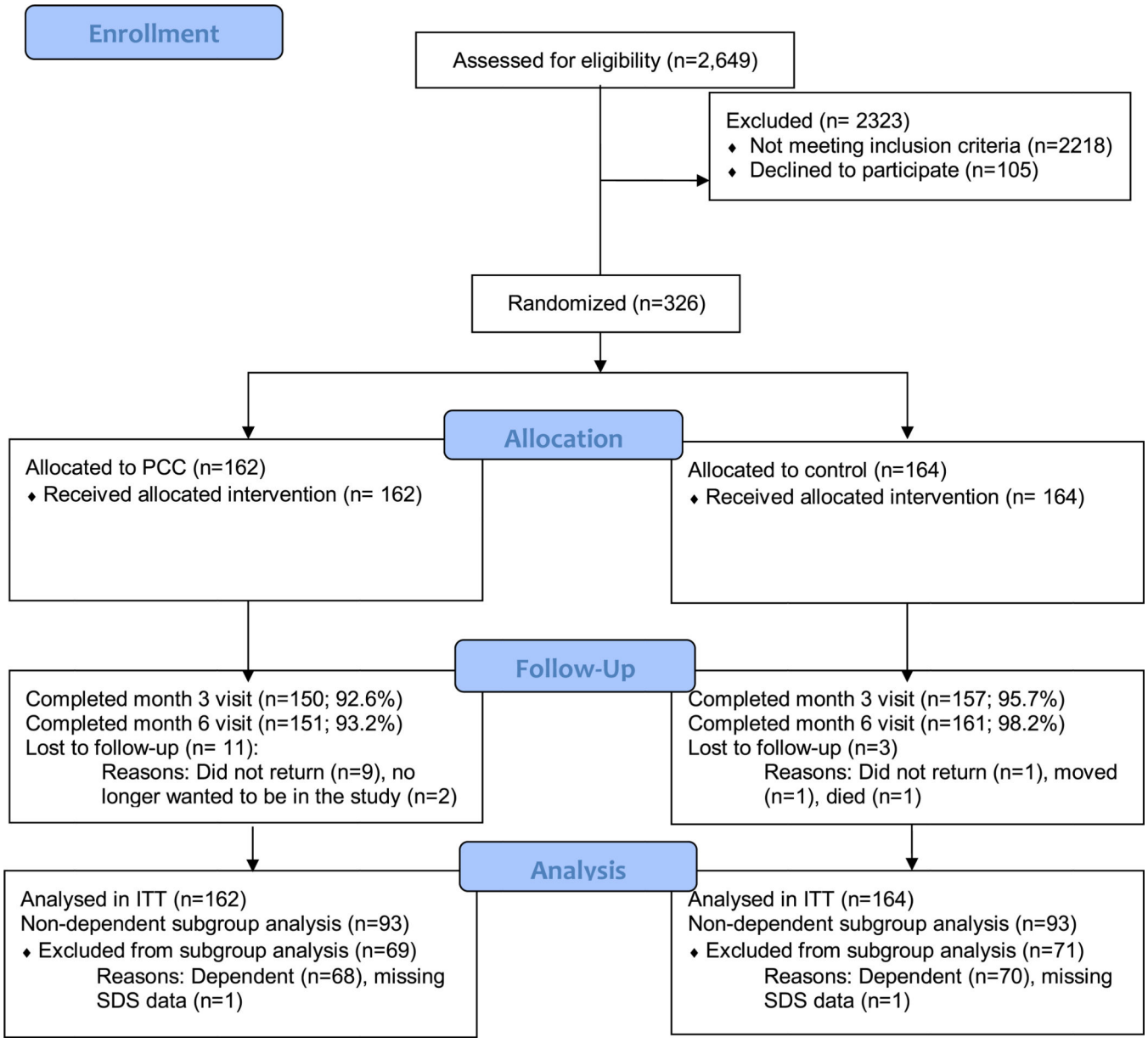

Fig. 1.

Flow diagram of Project ECHO participant enrollment, allocation, and retention, San Francisco, 2010–2012 *Legend*: *PCC* personalized cognitive counseling, *ITT* intent to treat, *SDS* severity of dependence scale

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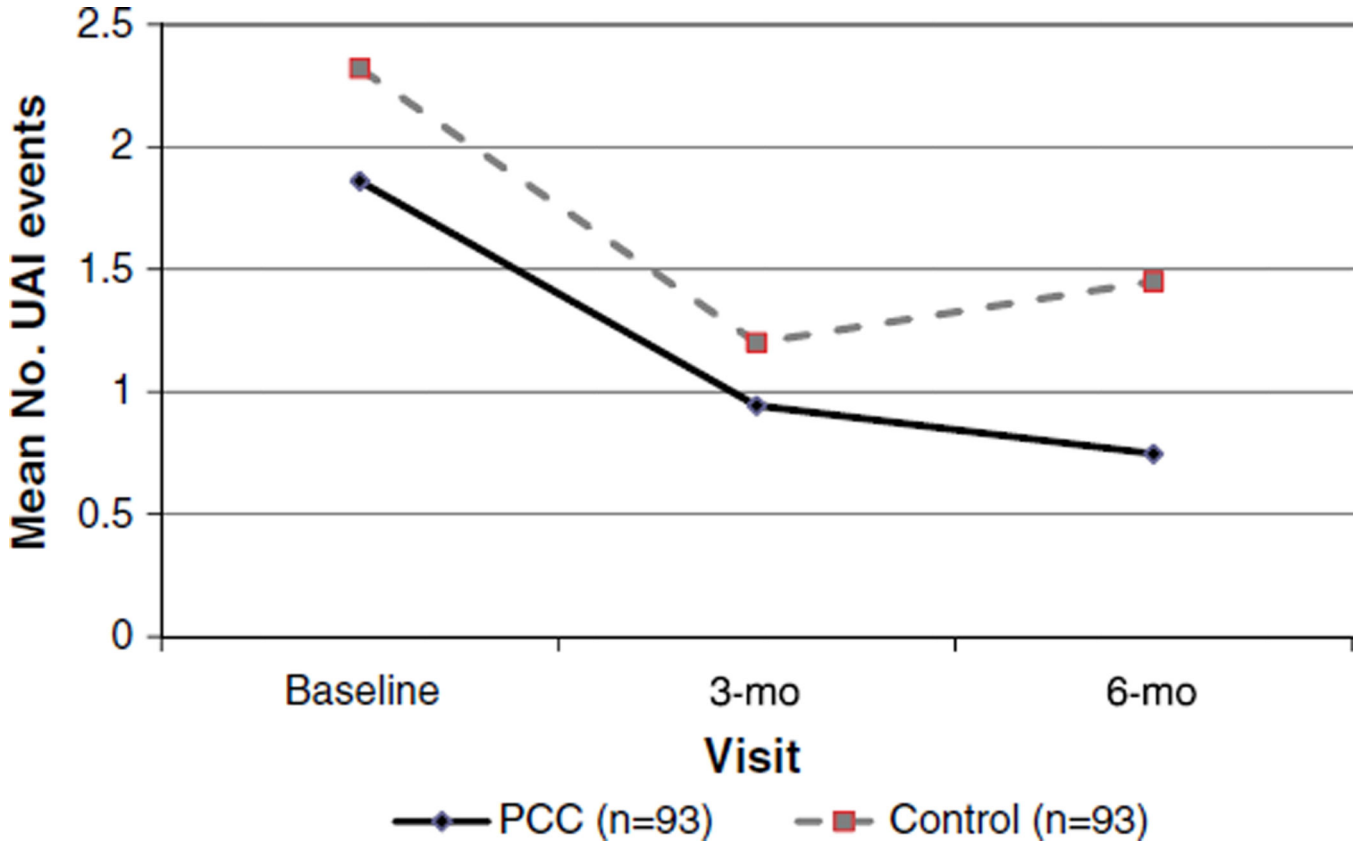

Fig. 2.

Unprotected anal intercourse with three most recent non-primary partners among non-dependent substance-using MSM (N = 186) by treatment arm, Project ECHO, San Francisco, 2010–2012 *Legend*: *UAI* unprotected anal intercourse, *PCC* personalized cognitive counseling

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Table 1

Most common self-justifications endorsed by PCC arm participants at baseline and 3-month follow-up

Self-justification ***I thought to myself something like:***	**Number who endorsed at baseline**	**Number who endorsed at 3-month visit**	**Number who endorsed at both visits[a]**
Part of me is saying this is risky, but another part is telling me to go for it	130	42	39
Alcohol and/or drugs make it easier to have sex (or different kinds of sex)	125	44	38
This feels more natural. Sex is just better without condoms	107	40	33
He said he was negative, and I have been tested. So it must be safe	106	38	26
I drank/used more than I'd planned and it just happened	106	21	21
I didn't want to fuck without a condom but the alcohol and/or drugs made me so horny I did it anyway	104	27	20
Topping isn't that risky	100	37	33
I didn't intend to have sex without a condom, but I was too fucked up and I couldn't think properly	95	28	16
This guy is really into me. It feels good to be wanted so much	90	29	22
He would have told me if he were positive	87	22	18
Condoms take all the feeling away	85	27	21
I'm still negative and I've done this before so it can't be that risky	83	33	25
Sex is better when I am drunk or high	80	30	26
All the alcohol and/or drugs have made me so horny, I just need to fuck	80	23	17
I know enough about this guy, I figure I can trust him	79	28	16

[a]Number of participants who completed 3-month self-justification elicitation instruments and persistently endorsed the respective self-justification at baseline and 3-month visit

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Table 2

Baseline characteristics of HIV-negative, episodic substance-using MSM

	Control N = 164 (%)	PCC N = 162 (%)	Test statistic[a]	*P* value
Demographics				
Age, mean (SD)	33.2 (9.6)	34 (10.5)	−0.58	0.56
Race/ethnicity			3.68	0.45
White	71 (44)	82 (51)		
Black	14(9)	17(11)		
Latino/Hispanic	48 (29)	38 (24)		
Asian and Pacific	21 (13)	14(9)		
Islander				
Other	9(6)	10(6)		
Country of birth			0.61	0.44
United States	137 (84)	130 (81)		
Outside United	26 (16)	31 (19)		
States				
Education			1.49	0.48
High school or less	22 (14)	15(9)		
Some college	114 (70)	116(72)		
College or above	27 (17)	30 (19)		
Income			2.23	0.52
Under $20,000	44 (27)	52 (32)		
$20,000–9,999	62 (38)	59 (37)		
$50,000–99,999	32 (20)	33 (21)		
$100,000 or above	25 (15)	17(11)		
Employment status			0.004	0.95
Not employed	41 (25)	40 (25)		
Employed	122 (75)	121 (75)		
HIV test history and medical				
Last HIV test			4.73	0.09
Less than 1 year	150 (92)	148 (92)		
Over 1 year ago	13(8)	9(6)		
Never	0(0)	4(2)		
Has regular health provider	105 (64)	98 (61)	0.44	0.51
Insurance			1.14	0.57
No insurance	52 (32)	52 (32)		
Private insurance	91 (56)	83 (52)		
Public insurance	20 (12)	26 (16)		
Self-reported substance use, past 3 months				
Methamphetamine	17 (10)	15(9)	0.11	0.74
Poppers	66 (40)	71 (44)	0.43	0.51

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	Control N = 164 (%)	**PCC N = 162 (%)**	**Test statistic[a]**	***P* value**
Cocaine (powdered or crack)	60 (37)	51 (32)	0.95	0.33
Binge-drinking (5 or more drinks on a single occasion)	149 (91)	142 (88)	0.91	0.34

[a]Wilcoxon ranksum *z* test statistic for age; Chi square test statistic for categorical variables

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Table 3

Effects of adapted personalized cognitive counseling (PCC) on primary and secondary sexual risk outcomes

	Mean			Rate of change in the mean value of outcomes over time			PCC vs control		
	Baseline	**3 month**	**6 month**	**Rate**	**95 % CI**	***P* value**	**RR**	**95 % CI**	***P* value**
Primary outcomes									
Number of unprotected anal into intercourse (UAI) events									
PCC	4.23	3.41	1.83	0.47	0.32–0.69	<0.001	1.03	0.58–1.83	0.91
Control	3.91	2.05	1.96	0.45	0.30–0.68	<0.001			
Number of unprotected anal into intercourse (UAI) partners									
PCC	2.71	1.54	1.27	0.46	0.32–0.65	<0.001	1.06	0.68–1.65	0.79
Control	2.60	1.37	1.16	0.43	0.33–0.57	<0.001			
Number of unprotected anal into intercourse (UAI) events with three most recent non-primary partners									
PCC	1.97	1.12	0.83	0.39	0.29–0.54	<0.001	0.75	0.51–1.12	0.17
Control	2.31	1.11	1.20	0.52	0.39–0.70	<0.001			
Secondary outcomes									
Number of serodiscordant unprotected anal intercourse (SDUAI) events									
PCC	1.06	0.43	0.34	0.28	0.18–0.45	<0.001	0.61	0.34–1.08	0.09
Control	1.13	0.49	0.55	0.47	0.31–0.71	<0.001			
Number of insertive UAI events									
PCC	2.84	2.80	1.37	0.55	0.35–0.84	0.006	1.34	0.69–2.58	0.39
Control	2.44	1.32	1.14	0.41	0.25–0.66	<0.001			
Number of receptive UAI events									
PCC	1.39	0.61	0.45	0.31	0.20–0.46	<0.001	0.57	0.33–1.01	0.052
Control	1.48	0.73	0.82	0.53	0.35–0.82	0.005			
Number of condom-protected anal intercourse events									
PCC	3.78	1.67	2.11	0.57	0.32–0.99	0.048	1.29	0.43–3.86	0.65
Control	2.83	2.13	1.29	0.44	0.17–1.13	0.089			

Legend Self-reported behaviors during past 3 months. Serodiscordant defined as having partner of discordant or of unknown HIV serostatus. RR indicates rate ratio (i.e. the ratio of the intervention and control rates of change in the mean value of the outcome over time, our summary measure of the intervention effect. The linearity assumption was checked); *CI* confidence interval, *UAI* unprotected anal intercourse